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ASTHMA & IMMUNOLOGY

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August 19, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fisher's Lane, Room 1061
Rockville, Maryland 20852
www.fda.gov/dockets/ecomments

RE: Docket Number: 2004N-0254

To Whom It May Concern:

On behalf of the over 4750 allergist, and specifically the approximately 2600 pediatric allergist members of the American Academy of Asthma, Allergy & Immunology (AAAAI), we are pleased to respond to the Food and Drug Administration's request for comments on the availability of medical devices intended to diagnose or treat diseases or conditions that affect children.

We feel strongly that more must be done to ensure that children benefit from devices designed and tested for use specifically in pediatric populations, rather than continue to use those that have been adopted or modified from adult use. Although many allergic diseases occur in both children and adults, there are definite differences with respect to disease diagnosis, treatment, and progression in children of differing ages, size, and developmental status.

Our comments draw from the experiences of pediatric allergy specialists involved in clinical care, clinical research, and basic science research on asthma and allergic and immunologic diseases of children.

***What are the unmet medical device needs in the pediatric population?***

- Better devices and standards to measure pulmonary function in infants and young children, including more affordable devices to use at home to monitor asthma.
- Devices for inhaled medications for infants and young children, to include better nebulizers, with shorter dosing times, and unit dose modules for a variety of medications.
- Dry powder inhalers for low inspiratory flow rates for use in younger children.
- Better devices for intranasal delivery of medications for infants and young children
- Auto-injectors for epinephrine with a broader range of doses suitable for infants and children.

In addition, there are some devices that currently exist, but, because of the lack of data, have questionable efficacy when used in infants and young children. For that reason, this suggestion has been made:

- Spacers/holding chambers that are designed and tested with specific medications in children so that pediatricians and specialists alike will be able to recommend combinations with documented efficacy.

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***What are the possible barriers to the development of new pediatric devices? Are there regulatory hurdles? Clinical hindrances? Economic issues? Legal issues?***

We believe that there are barriers that involve all of these issues. Specifically we feel that the following barriers are most important in our specialty:

- Lack of accepted parameters of efficacy other than pulmonary function tests when studying asthma in children.
- Reluctance to study specific devices with specific medications, for fear of "marrying" a device to a medication. For example, spacers/holding chambers are used with medications in clinical practice, and are recommended for use by national expert panels. However, we need to be able to make choices based on data generated from studies of individual spacers/holding chambers with medications other than those for which they have been recommended.
- Need for a placebo arm in clinical studies for NDAs often hinders recruitment.
- Funding for novel uses for pediatric devices is often lacking and there are insufficient incentives for manufacturers to sponsor studies in children.
- There is reluctance to accept data from small independent studies.

***What could the FDA do to facilitate the development of devices intended for the pediatric market? Are there changes to the law, regulation, or premarket process that would encourage clinical investigators, sponsors, and manufacturers to pursue clinical trials and/or marketing of pediatric devices?***

We would like to make the following suggestions:

- Develop standards for parameters of efficacy in children that do not depend on measures of pulmonary function, and accept those parameters as proof of efficacy
- Design studies of new medications so that the drugs or devices will be studied in the ways in which they will be used clinically. For example, insist that all new HFA devices that will have pediatric labeling be studied with spacers/holding chambers.
- Allow studies without placebo arms for infants and young children, to improve the ability to recruit patients.
- Have device manufacturers pay a portion of profits to fund studies on the use of these devices with other medications, or in other age groups.

Sincerely,

Michael Schatz, MD MS
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F. Estelle R. Simons, MD
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Chair, Ad Hoc Pediatric Asthma Task Force

Cc: Elaine Vining, Assistant Director, American Academy of Pediatrics